

### **REMARKS**

Claims 1-21, 23-29, and 31-35 are pending at the time of this action. Independent claims 1, 11, 21, and 27 are amended herein. Reconsideration and allowance of the above-referenced application are respectfully requested.

#### **Rejections under 35 U.S.C. §103**

Claims 1-3, 5-9, 11-17, 19, 21, 23, 25, and 26 stand rejected as allegedly being obvious over European Journal of Cardio-thoracic Surgery 13 (1988) 240-246 ("Maisano") in view of U.S. Patent No. 6,355,030 ("Aldrich"). Applicants respectfully traverse the rejection as Maisano and Aldrich, both alone and in combination, fail to teach or suggest each and every element of the claims.

#### **Claim 1**

Claim 1 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having a first structure releasably coupled thereto;

deploying the first structure from the catheter directly on an annulus of the heart valve, the first structure adapted to modify the annulus so as to reduce regurgitation in the heart valve; and

in combination with deploying the first structure from the catheter directly on the annulus of the heart valve, deploying a second structure from the same catheter directly on the leaflets, wherein the second structure holds leaflets of the heart valve together so as to reduce regurgitation in the heart valve.

Maisano fails to disclose or suggest, *inter alia*, deploying a second structure directly on the leaflets from the same catheter that deployed a first structure directly on the annulus. Instead, Maisano discloses the use of two separate catheters in two separate procedures. Maisano discloses performing a double orifice repair in a redo procedure on a patient that had previously received a Carpentier annuloplasty procedure. ("A double orifice repair was carried out in the redo patient ... after previous Carpentier annuloplasty. In this case, the procedure was

successfully carried out leaving the previously implanted ring in site.” Maisano, page 242.) Because the double orifice repair in Maisano is performed in a subsequent, separate procedure to the annuloplasty, it would be highly unlikely, if not impossible, to perform both the double orifice repair and the annuloplasty using the same catheter.

Moreover, Maisano fails to disclose or suggest deploying a structure from a catheter directly on the annulus of the heart valve. In Maisano, a catheter is not used to deploy a structure on the annulus of the heart valve. Rather, Maisano discloses that a double orifice repair is performed *surgically* via a conventional midline sternotomy. Maisano provides no disclosure whatsoever that would enable one of ordinary skill in the art to deploy a structure from a catheter directly on the annulus of the heart valve. Nor does Maisano disclose deploying a second structure from the same catheter (or any catheter) directly on the leaflets. Even if one of ordinary skill in the art were motivated to deploy a structure from a catheter directly on the annulus or directly on the leaflets, it would have been beyond the skill in the art at the time of the invention to modify the Maisano procedure to use a catheter for deployment. It would require significant engineering and procedural modifications in order to enable a catheter to deploy a structure directly on the annulus or leaflets. There is no motivation or suggestion in Maisano or Aldrich for such modifications.

Aldrich also fails to disclose or suggest deploying a second structure directly on the leaflets from the same catheter that deployed a first structure directly on the annulus. Aldrich merely relates to a thermal heating member that supplies thermal energy to a heart valve. Aldrich makes no mention whatsoever of deploying a second structure directly on the leaflets from the same catheter that deployed a first structure directly on the annulus.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1. Claims 2, 3, and 5-9 all depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Maisano or Aldrich. Claims 4 and 10 were rejected as being unpatentable over Maisano in view of Aldrich and further in view of U.S. Patent No. 5,593,435 to Carpentier.

Claims 4 and 10 both depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1 as well as on their own merit.

**Claim 11**

Claim 11 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

implanting the annuloplasty device from the catheter directly on an annulus of the heart valve to modify the annulus of the heart valve and reduce regurgitation in the heart valve;

in combination with implanting an annuloplasty device from the catheter directly on an annulus of the heart valve, deploying a structure that directly attaches to a first valve leaflet and a second valve leaflet of the heart valve so as to reduce regurgitation in the heart valve wherein the structure is deployed during the same procedure in which the annuloplasty device is implanted.

Maisano fails to disclose or suggest, *inter alia*, deploying a structure that directly attaches to a first valve leaflet and a second valve leaflet of the heart valve wherein the structure is deployed during the same procedure in which the annuloplasty device is implanted. As discussed above, Maisano discloses performing a first annuloplasty procedure on a patient and subsequently performing a double orifice repair in a separate procedure. Maisano makes no mention of performing both the annuloplasty and the double orifice repair in the same procedure. Aldrich fails to provide the missing teaching.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11. Claims 12-17 and 19 all depend from claim 11 and are patentable over the prior art for at least those reasons articulated with respect to claim 11. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Maisano or Aldrich. Claims 18 and 20 were rejected as being unpatentable over Maisano in view of Aldrich and further in view of Carpentier. Claims 18 and 20 both depend

from claim 11 and are patentable over the prior art for at least those reasons articulated with respect to claim 11 as well as on their own merit.

**Claim 21**

Claim 21 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

implanting the annuloplasty device from the catheter directly on an annulus of the heart valve to effect a geometric change in an annulus of the heart valve so as to reduce regurgitation in the heart valve; and

in combination with effecting a geometric change in an annulus of the heart valve, coapting leaflets of the heart valve by attaching a structure from the same catheter directly to the leaflets so as to reduce regurgitation in the heart valve.

Maisano fails to disclose or suggest, *inter alia*, d coapting leaflets of the heart valve by attaching a structure from the same catheter that implanted an annuloplasty device directly on an annulus of the heart valve. As discussed above with reference to claim 1, Maisano discloses using two separate procedures, which necessitates the use of two separate catheters. Aldrich fails to provide the missing teaching.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 21. Claims 23, 25, and 26 all depend from claim 21 and are patentable over the prior art for at least those reasons articulated with respect to claim 21. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Maisano or Aldrich. Claim 24 was rejected as being unpatentable over Maisano in view of Aldrich and further in view of Carpentier. Claim 24 depends from claim 21 and is patentable over the prior art for at least those reasons articulated with respect to claim 21 as well as on its own merit.

**Claim 27**

Claims 27-29 and 31-35 stand rejected as allegedly being obvious over Maisano in view of Aldrich and further in view of Carpentier.

Claim 27 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

implanting the annuloplasty device on the annulus of the heart valve so that the annuloplasty device is positioned on an atrial side of the annulus of the heart valve to modify the annulus of the heart valve and reduce regurgitation in the heart valve;

in combination with implanting an annuloplasty device at the heart valve, holding leaflets of the heart valve together at one or more adjacent locations in a manner that reduces regurgitation in the valve wherein the leaflets are held together during the same procedure in which the annuloplasty device is implanted.

Maisano fails to disclose or suggest, *inter alia*, holding leaflets of the heart valve together wherein the leaflets are held together during the same procedure in which the annuloplasty device is implanted. As discussed above with reference to claim 11, Maisano discloses performing a first annuloplasty procedure on a patient and subsequently performing a separate double orifice repair procedure. Maisano makes no mention of performing both the annuloplasty and the double orifice repair in the same procedure. Both Aldrich and Carpentier fail to provide the missing teaching.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 27. Claims 28-29 and 31-35 all depend from claim 27 and are patentable over the prior art for at least those reasons articulated with respect to claim 27. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by the cited art.


**Conclusion**

The above is believed to be a complete response. In view of the amendments and remarks herein, Applicants believe that all claims are now in condition for allowance and ask that these pending claims be allowed. The foregoing comments made with respect to the positions taken by the Examiner are not to be construed as acquiescence with other positions of the Examiner that have not been explicitly contested. Accordingly, the arguments for patentability of a claim should not be construed as implying that there are not other valid reasons for patentability of that claim or other claims. The Examiner is invited to telephone the undersigned to resolve any remaining issues and/or informalities and expedite prosecution of this case.

Please apply any required charges or credits to Deposit Account No. 50-0311.

Respectfully submitted,

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